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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/826,136 | 04/16/2004 | Nobert Hofgen | HUBR-1261-US | 8765 |
| 24972 | 7590 | 02/10/2006 | EXAMINER | |
| FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198 | | | BALLS, ROBERT J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1625 | |
| DATE MAILED: 02/10/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/826,136 | Applicant(s) HOFGEN ET AL. | |
| | Examiner James Balls | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 10-17, 21-26 and 1-2, 8-9, 18-20 (in part) is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 3, 4-5 and 1-2, 8-9, 18-20 (in part) is/are rejected.
- 7) ☒ Claim(s) 1,2,8,9 and 18-20 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1 – 26 are pending. Claims 22-26 are new claims drawn to non-elected inventions.

Election / Restriction

2. New Claims 22-26 are drawn to non-elected inventions. New Claim 22 belongs with Claim 14 in Group IV of the previous restriction requirement. New Claim 23 belongs in with Claim 15 in Group V of the previous restriction requirement. New Claim 24 belongs with Claim 16 in Group VI of the previous restriction requirement. New claim 25 belongs with Claim 17 in Group VII of the previous restriction requirement and Claim 26 belongs with Claims 1-2, 4-5, 7-13 and 21 in Group III of the previous restriction requirement.

In response to the restriction requirement mailed on October 21, 2005, Applicants have elected with traverse to prosecute the claims of Group I, drawn to compounds and compositions of formula I in which A is N and B is N-O. Applicants did not distinctly and specifically point out the supposed errors in the Restriction Requirement and therefore the election has been treated as an election without traverse (MPEP §818.03(a)). Groups II – VII are withdrawn from further considerations as being drawn to a non-elected invention.

Objections

4. Claims 1-2, 8-9, and 18-20 are objected to for containing language drawn to non-elected inventions. Correction is required.

Double Patenting

5. Claims 3 and 1-2, 4-5, 8-9, 18-20 (in part), are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, and 9-18 of copending Application No.10/399,051 in view of Armin Hatzelmann & Christian Schudt, *Anti-Inflammatory and Immunomodulatory Potential of the Novel PDE4 Inhibitor Roflumilast in Vitro*, Journal of Pharmacology & Experimental Therapeutics, 397:267-279 (April 2004). This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 UPQ 64 (CCPA 1969).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to one skilled in the art to make the pyridine N-oxide derivatives of the compounds disclosed in the copending application in light of Hatzelmann & Schudt and expect those compounds to function as phosphodiesterase-4 inhibitors. The conflicting claims encompass a core structure of N-(pyridin-4yl)-7-azaindol-3yl-glyoxyamide whereas the current claims are drawn to the N-oxide pyridine derivatives of N-(pyridin-4yl)-7-azaindol-3yl-glyoxyamide. In other words, the only difference between the compounds disclosed in the two applications is the addition of oxygen to a pyridine nitrogen. A person of ordinary skill in the art would expect N-(pyridin-4yl)-7-azaindol-3yl-glyoxyamides and its N-oxide pyridine derivatives to function similarly (i.e. to function as phosphodiesterase-4 inhibitors). Hatzelmann & Schudt compared roflumilast, a potent phosphodiesterase-4 inhibitor, with its N-oxide pyridine derivative and found that both compounds inhibit phosphodiesterase-4 (see page 277, first paragraph of the Discussion section.) Likewise, one of ordinary skill in the art can look at the phosphodiesterase-4 inhibitors disclosed in the claims of the copending

application and expect that the N-oxide pyridine derivatives of those compounds would also inhibit phosphodiesterase-4.

A timely filed terminal disclaimer in compliance with 37 C.F.R. §1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 D.F.R. §1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Conclusion

6. No claims are allowed.

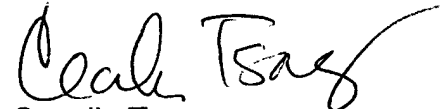
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1625

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James Balls
Art Unit 1625
February 2, 2006



Cecelia Tsang
Supervisory Patent Examiner
Art Unit 1625